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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/593,827 06/13/00 GUD

S LIFE-008

EXAMINER

HM22/0926

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CHAUDHRY, M

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

09/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Applicati n N .

09/593,827

Applicant(s)

GUO ET AL.

Examiner

Mahreen Chaudhry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

Art Unit: 1623

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,972,294 issued to Smith et al. Smith et al. disclose a reagent test strip for use in the measurement of blood glucose. Smith et al. disclose that the reagent test strip comprises a polysulfone membrane, 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino) phenothiazine, glucose oxidase and horseradish peroxidase (Column 11, Lines 50+). Smith et al. further disclose that the test strip may be in an absorbance reading apparatus and that the timing of the measurement occurs automatically (Column 5, Lines 7-22; Column 3, Lines 58+). Smith et al. disclose that the change in reflectance is correlated with the glucose concentration in the sample (Column 7, Lines 17-19). Smith et al. exemplify polysulfones and nylons as appropriate porous matrix materials (Column 6, Lines 29-42).

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1623

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al.

The applicability of Smith et al. to the instant invention has been discussed above. Smith et al.

do not expressly disclose a kit comprising a reagent test strip, a means for obtaining a blood sample and an analyte standard. However, Smith et al. do teach that a sample of whole blood is placed on the surface of the test strip (Column 2, Lines 38-40). Although Smith et al. do not specifically disclose the means by which such a blood sample is obtained, such means would certainly have been obvious to one having ordinary skill in the art at the time of the invention.

Furthermore, although Smith et al. do not specifically disclose a glucose standard, the use of such standards for comparison with test samples is conventional in the art and therefore, inclusion of a glucose standard, a means for obtaining a blood sample and a reagent test strip in a single package would have been obvious to one having ordinary skill in the art.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,445,944 issued to Ullman discloses a composition for detecting peroxidatively active substances comprising fluorescers such as phenoxazine.

U.S. Patent 5,362,633 issued to Puglia discloses a method for detecting peroxidatively active substances comprising diphenylamine as an indicator dye.

Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc  
September 13, 2001



GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600